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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,052

03/22/2006

Giovanni Meazza

163-689

8978

7590 02/12/2008
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EXAMINER

HAVLIN, ROBERT H

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

02/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,052	Applicant(s) MEAZZA ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/22/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims: Claims 1-16 are currently pending.

Priority: This application is a 371 of PCT/EP04/10653 (09/21/2004) and claims foreign priority to ITALY MI2003A 001855 (09/29/2003).

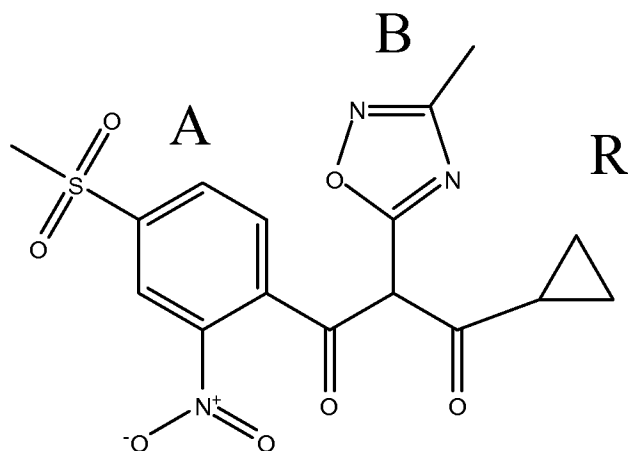
IDS: The IDS dated 3/22/2006 was considered.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1, 2, and 13-16; product of Formula I) in the reply filed on 12/3/2007 is acknowledged. The traversal is on the ground(s) that there is unity of invention. This is not found persuasive because the common technical feature linking the claims is a propyl-1,3-dione which are well known in the prior art and is disclosed in numerous references including the IDS document PL 171529. Therefore, the technical feature is not a contribution over the prior art and the claims are properly restricted.

The requirement is still deemed proper and is therefore made FINAL.

Applicant also elected the species of compound No. 22 (Table 1 on page 163; claims 1, 2, and 13-16 reading thereupon):



1-cyclopropyl-2-(3-methyl-1,2,4-oxadiazol-5-yl)-3-(4-(methylsulfonyl)-2-nitrophenyl)propane-1,3-dione

The examiner has searched the elected species; however as described in the following rejections no generic claim was found patentable. Therefore, the claims are restricted to the elected species and the remaining subject matter withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1, 2, and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the definitions of the variables in the claims, it is not clear what the alternatives corresponding to the applicant's invention. For example, "R" and "A" as shown below does not clearly delineate which are the substituents and the substituted groups. There are numerous other examples in the claims where one of ordinary skill in the art would not be able to determine the metes and bounds of the claims based on the claim language and the specification, therefore

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the claims are indefinite. The examiner attempted to get clarification on this matter by contacting James Costigan at 212-302-8989 on 2/7/2008, but the examiner was unsuccessful.

A represents:

R represents a hydrogen atom, a linear or branched C₁-C₆ alkyl group, a linear or branched C₁-C₆ haloalkyl group, a C₃-C₆ cycloalkyl or C₄-C₁₂ cyclo-alkylalkyl group optionally substituted with halogen atoms or C₁-C₆ alkyl or C₁-C₆ thioalkyl or C₁-C₆ alkoxy or C₁-C₆ alkoxy carbonyl groups, C₂-C₆ alkenyl groups, C₂-C₆ alkynyl groups, the latter two groups, in turn, optionally substituted with halogen atoms, a C₃-C₆ cycloalkenyl group optionally substituted with halogen atoms or C₁-C₆ alkyl groups, an aryl or arylalkyl group optionally substituted;

an aryl group optionally substituted by one or more substituents selected from halogen, NO₂, CN, CHO, OH, linear or branched C₁-C₆ alkyl, linear or branched C₁-C₆ haloalkyl, linear or branched C₁-C₆ alkoxy, linear or branched C₁-C₆ haloalkoxy, C₁-C₆ cyanoalkyl, C₁-C₆ alkoxyalkyl, C₂-C₆ alkylthioalkyl, C₂-C₆ alkylsulfinylalkyl, C₂-C₆ alkylsulfonylalkyl, C₂-C₆ haloalkoxyalkyl, C₂-C₆ haloalkylthioalkyl, C₂-C₆ haloalkylsulfinylalkyl, C₂-C₆ haloalkylsulfonylalkyl, C₂-C₆ alkoxyalkoxy or C₂-C₆ haloalkoxyalkoxy optionally substituted with a group selected from C₁-C₄ alkoxy or C₁-C₄ haloalkoxy, C₂-C₆ alkylthioalkoxy, C₂-C₆ haloalkylthioalkoxy, C₃-C₁₂ dialkoxyalkyl, C₃-C₁₂ dialkylthioalkyl, C₃-C₁₂ dialkylthioalkoxy, C₃-C₁₂ dialkoxyalkoxy, C₂-C₆ haloalkoxyhaloalkoxy, C₃-C₁₀ alkoxyalkoxyalkyl, C₂-C₆ alkenyl, C₂-C₆ haloalkenyl, C₂-C₆ alkenyloxy, C₂-C₆ haloalkenyloxy, C₂-C₆ alkenyloxyalkoxy, C₃-C₈ haloalkenyloxyalkoxy, C₂-C₆ alkynyl, C₂-C₆ haloalkynyl, C₂-C₆ alkynyloxy, C₂-C₆ haloalkynyloxy, C₃-C₈ alkynyloxyalkoxy, C₃-C₈ haloalkynyloxyalkoxy, C₃-C₁₂ acylaminoalkoxy, C₂-C₆ alkoxyiminoalkyl, C₂-C₆ haloalkoxyiminoalkyl, C₃-C₈ alkenyloxyiminoalkyl, C₃-C₈ haloalkenyloxyiminoalkyl, C₃-C₈ alkynyloxy-

4. Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims use the term "active principle" which is not defined in the specification and would not convey clear meaning to one of ordinary skill in the art. Therefore, the claims are indefinite.

5. Claims 2, 13-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of Formula I does not reasonably provide enablement for isomers of these compounds. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. The nature of the invention,
2. The state of the prior art,
3. The predictability or lack thereof in the art,
4. The amount of direction or guidance present,
5. The presence or absence of working examples,
6. The breadth of the claims,
7. The quantity of experimentation needed, and
8. The level of the skill in the art.

The nature of the invention

The nature of the invention is compounds of Formula I and isomers thereof.

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that an isomer is any compound having the same composition, including constitutional isomers, which are compounds whose atoms are connected differently and stereoisomers. Constitutional isomers can contain different functional groups in varying positions.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is for the compounds of Formual I. There is no direction or guidance at to what type of isomers are included in the claims.

There is no data present in the instant specification for the preparation of any type of isomer, such as constitutional isomers.

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The breadth of the claims

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include any isomer, i.e. any compound with the same number of each atom.

The quantity or experimentation needed and the level of skill in the art

While the level of the skill in the pharmaceutical arts is high, it would require undue experimentation of one of ordinary skill in the art to prepare any isomer as instantly claimed since an isomer of the compounds need only have the same composition of atoms, not necessarily the same order of atoms and can have varying functional groups in varying positions. Therefore, the claims lack enablement for isomers.

This rejection can be overcome by deleting all instances of “and isomers”.

Conclusion

No claim is in condition for allowance.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626